



Attorney's Docket No. 3119 R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chen et al.)
Serial No: 10/628,984) Group Art Unit: Unassigned
Filed: 07/28/03)) Examiner: Unassigned
For: Injectable Multimodal Polymer Depot Compositions And)
Uses Thereof)
)

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit herewith patents, publications and other information of which they are aware, which they believe an examiner may consider to be material to the patentability of the claims of this application, and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

While this Information Disclosure Statement may contain "material" information pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to herein is either "material" or "prior art" to the invention disclosed and claimed in the above-referenced application unless specifically designated as such. Applicants specifically reserve the right, where appropriate, to avoid or antedate any such reference by the appropriate arguments or showings under 37 C.F.R. § 1.131 and § 1.608, or any other appropriate means.

A completed PTO Form 1449 listing each reference which is not a U.S. Patent application is submitted herewith, and it respectfully requested that an Examiner initialed copy of the PTO Form 1449 be returned to the undersigned.

A copy of each reference therein listed accompanies this Information Disclosure Statement.

-OR-

NO copies of the references therein listed accompany this Information Disclosure Statement under 37 C.F.R. § 1.98(d), as each was previously cited by or submitted to the Patent Office in prior

application Serial No. 09/129,687, filed 08/05/98, which this application relies upon for an earlier filing date under 35 U.S.C. § 120.

This Information Disclosure Statement is not a representation that a search has been made or that no other information material to the patentability of this invention exists.

- [] This Information Disclosure Statement is being filed within three months of the filing or entry of the national stage of this application, or before the mailing of a first Office Action on the merits, whichever is later. No fee is required under 37 C.F.R. § 1.97(b). However, in the event that more than 90 days from filing have elapsed and a first Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the fee required under 37 C.F.R. 1.17(p) to Deposit Account Number 01-1173.
- This Information Disclosure Statement is being submitted *after* three months from the date of filing or entry of the national stage or this application, or *after* the mailing of a first Office Action, whichever is later, but *before* the mailing date of either a final Office Action or a Notice of Allowance.
- The Commissioner is hereby authorized to charge the fee required under 37 C.F.R. § 1.17(p) to Deposit Account 10-0750.
- OR-**
- Certification as specified in 37 C.F.R. § 1.97(e) follows:
- Each* item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application no more than three months prior to the filing of this statement.
- No* item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

The Examiner is hereby requested to consider these references and other information and make them of record in the above-referenced application. Applicants respectfully submit that the claims of this application are patentable over the above-cited references and information. Examination and allowance of this application at an early date are requested.

Respectfully submitted,

Date:

9/10/03

By:

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Robert R. Nekler, Reg. No. 46,950

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313 on September *12*, 2003.

ALZA CORPORATION

BY: *Jolanta Pence*
Jolanta Pence

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INFORMATION DISCLOSURE CITATION Sheet 1 of 1 PTO-1449			ATTORNEY'S DOCKET NO.:		APPLICATION NO.:			
			ARC 3119 R1		10/628,984			
			APPLICANT: Chen et al.					
			FILING DATE: 07/28/03		GROUP: Unassigned			
US PATENT DOCUMENTS								
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLAS S	FILING DATE		
	3,797,492	3/19/74	Place	128	260	12/27/72		
	3,923,939	12/2/75	Baker et al.	264	49	6/7/74		
	3,987,790	10/26/76	Eckenhoff et al.	128	260	10/1/75		
	4,008,719	2/22/77	Theeuwes et al.	128	260	2/2/76		
	4,443,340	4/17/84	May et al.	210	697	5/24/83		
	4,586,559	2/4/86	Nuwayser et al.	427	3	2/6/84		
	4,623,588	11/18/86	Nuwayser et al.	428	402.24	12/2/85		
	4,668,506	5/26/87	Bawa	424	429	8/16/85		
	4,708,861	11/24/87	Popescu et al.	424	1.1	1/31/85		
	4,711,782	12/8/87	Okada et al.	424	455	12/11/86		
	4,713,244	12/15/87	Bawa et al.	424	429	8/16/85		
	4,853,218	8/1/89	Yim et al.	424	85.7	2/24/87		
	4,865,845	9/12/89	Eckenhoff et al.	424	424	9/12/89		
	4,866,050	9/12/89	Ben-Amoz	514	179	4/27/88		
	4,931,279	6/5/90	Bawa et al.	424	427	7/21/88		
	4,938,763	7/3/90	Dunn et al.	604	891.1	10/03/88		
	4,985,404	1/15/91	Mitchell et al.	514	6	6/29/88		
	5,019,400	5/28/91	Gombotz et al.	424	497	5/1/89		
	5,057,318	10/15/91	Magruder et al.	424	438	4/23/90		
	5,059,423	10/22/91	Magruder et al.	424	438	4/23/90		
	5,061,492	10/29/91	Okada et al.	424	423	1/24/90		
	5,077,033	12/31/91	Viegas et al.	514	668	8/7/90		
	5,085,866	2/4/92	Cowsar et al.	424	481	12/2/88		
	5,112,614	5/12/92	Magruder et al.	424	422	9/14/89		
	5,137,727	8/11/92	Eckenhoff et al.	424	422	6/12/91		
	5,151,093	9/29/92	Theeuwes et al.	604	892.1	10/29/90		
	5,181,914	1/26/93	Zook	604	307	5/6/92		
	5,209,746	5/11/93	Balaban et al.	604	892.1	2/18/92		
	5,234,692	8/10/93	Magruder et al.	424	473	9/2/92		
EXAMINER:			DATE CONSIDERED:					

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INFORMATION DISCLOSURE CITATION Sheet 1 of 2 PTO-1449			ATTORNEY'S DOCKET NO.: ARC 3119 R1		APPLICATION NO.: 10/628,984	
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US PATENT DOCUMENTS						
	5,234,693	8/10/93	Magruder et al.	424	473	9/2/92
	5,242,910	9/7/93	Damanj	514	152	10/13/92
	5,252,318	10/12/93	Joshi et al.	424	78.04	6/15/90
	5,278,201	1/11/94	Dunn et al.	523	133	4/24/90
	5,279,608	1/18/94	Cheikh	604	892.1	12/4/91
	5,308,348	5/3/94	Balaban et al.	644	891.1	5/5/93
	5,310,865	5/10/94	Katashi Enomoto et al.	528	361	12/18/92
	5,324,519	6/28/94	Dunn et al.	424	426	10/28/91
	5,300,295	8/5/94	Viegas et al.	424	427	9/13/91
	5,336,057	8/9/94	Toshio Fukuda et al.	417	395	7/20/93
	5,330,452	7/19/94	Zook	604	307	6/1/93
	5,340,614	8/23/94	Perman et al.	427	2.24	2/11/93
	5,342,627	8/30/627	Chopra et al.	424	473	11/12/92
	5,415,866	5/16/95	Zook	424	448	7/12/93
	5,540,912	7/30/96	Roorda et al.	424	422	3/30/93
	5,441,732	8/15/95	Hoeg et al.	424	78.04	3/18/92
	5,447,725	9/5/95	Damani et al.	424	435	6/11/93
	5,456,679	10/10/95	Balaban et al.	604	892.1	12/7/94
	5,487,897	1/30/96	Polson et al.	424	426	9/28/93
	5,540,912	7/30/96	Roorda et al.	424	422	7/30/96
	5,543,156	8/6/96	Roorda et al.	424	484	1/21/94
	5,556,905	9/17/96	Frappier et al.	524	311	3/30/94
	5,571,525	11/5/96	Roorda et al.	424	426	3/30/94
	5,787,175	12/24/96	Viegas et al.	424	427	12/28/93
	5,599,534	2/4/97	Himmelstein et al.	424	78.04	8/9/94
	5,599,552	2/4/97	Dunn et al.	424	423	5/26/94
	5,610,184	3/11/97	Shahinian, Jr.	514	540	3/3/95
	5,618,563	4/8/97	Berde et al.	424	501	9/10/93
	5,620,700	4/15/97	Berggen et al.	424	435	5/9/95
	5,651,986	7/29/97	Brem et al.	424	484	6/14/96
	5,654,010	8/5/97	Johnson et al.	424	502	7/7/95
EXAMINER:				DATE CONSIDERED:		

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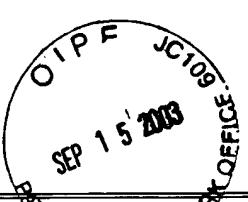
INFORMATION DISCLOSURE CITATION Sheet 1 of 3 PTO-1449			ATTORNEY'S DOCKET NO.: ARC 3119 R1	APPLICATION NO.: 10/628,984		
			APPLICANT: Chen et al.			
			FILING DATE: 07/28/03	GROUP: Unassigned		
US PATENT DOCUMENTS						
	5,656,297	8/12/97	Bernstein et al.	424	484	5/3/94
	5,660,817	8/26/97	Masterman et al.	424	49	11/9/94
	5,674,292	10/7/97	Tucker et al.	623	16	7/7/95
	5,618,563	4/8/97	Berde et al.	424	501	9/10/93
	5,681,873	10/28,97	Norton et al.	523	115	10/14/93
	5,700,485	12/23/97	Berde et al.	424	501	5/1/95
	5,707,664	1/13/98	Illum	424	434	12/20/94
	5,708,011	1/13/98	Bardsley et al.	514	330	10/13/94
	5,733,950	3/31/98	Dunn et al.	523	113	9/25/95
	5,744,153	4/28/98	Yewey et al.	424	426	6/9/97
	5,747,058	5/5/98	Tipton et al.	424	337	6/7/95
	5,747,060	5/5/98	Sackler et al.	424	426	3/26/96
	5,759,563	6/2/98	Yewey et al.	424	426	6/7/95
	5,760,077	6/2/98	Shahinian Jr.	514	540	3/11/97
	5,766,637	6/16/98	Shine et al.	424	497	10/8/96
	5,780,044	7/14/98	Yewey et al.	424	426	12/5/96
	5,783,205	7/21/98	Berggren et al.	424	426	4/10/97
	5,804,212	9/8/98	Illum	424	434	6/17/97
	5,849,763	12/15/98	Bardsley et al.	514	445	10/27/95
	5,910,502	6/8/99	Gennery	514	330	3/3/98
	5,922,340	7/13/99	Berde et al.	424	426	9/16/96
	5,942,241	8/24/99	Chasin et al.	424	426	6/7/96
	5,955,479	9/21/99	Bardsley et al.	514	330	10/13/94
	5,958,443	9/28/99	Viegas et al.	424	427	12/23/96
	5,972,326	10/26/99	Galin et al.	424	78.04	3/18/97
	5,972,366	10/26/99	Haynes et al.	424	422	9/17/96
	5,990,194	11/23/99	Dunn et al.	523	113	11/7/97
	5,919,835	7/6/99	Domb et al.	523	113	12/23/92
	6,004,295	12/21/99	Langer et al.	604	164	6/26/98
	6,046,187	4/4/00	Berde et al.	514	180	9/16/96
	6,050,986	4/18/00	Hektnar	604	508	12/1/97
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INFORMATION DISCLOSURE CITATION Sheet 1 of 4 PTO-1449			ATTORNEY'S DOCKET NO.: ARC 3119 R1		APPLICATION NO.: 10/628,984	
			APPLICANT: Chen et al.			
			FILING DATE: 07/28/03	GROUP: Unassigned		
US PATENT DOCUMENTS						
	6,086,909	7/11/00	Harrison et al.	424	430	2/12/99
	6,103,266	8/15/00	Tapolski et al.	424	484	4/22/98
	6,106,301	8/22/00	Merril	434	262	9/4/97
	6,117,425	9/12/00	McPhee et al.	424	94.64	7/7/95
	6,120,789	9/19/00	Dunn	424	426	3/30/99
	6,120,804	9/19/00	Drizen et al.	424	488	4/8/99
	6,129,933	10/10/00	Oshlack et al.	424	495	7/24/97
	6,130,200	10/10/00	Brodbeck et al.	514	2	12/18/97
	6,136,334	10/24/00	Viegas et al.	424	427	6/11/97
	6,143,314	11/7/00	Chandeashekhar et al.	424	426	10/28/98
	6,193,991	2/27/01	Shukla	424	426	10/28/98
	6,193,994	2/27/01	Lee et al.	424	444	5/22/97
	6,197,327	3/6/01	Harrison et al.	424	430	5/15/98
	6,214,387	4/10/01	Berde et al.	424	501	9/17/97
	6,217,911	4/17/01	Vaung et al.	424	501	7/5/96
	6,238,702	5/29/01	Berde et al.	424	489	7/12/99
	6,248,345	6/19/01	Goldenheim et al.	424	426	7/2/98
	6,255,502	7/3/01	Penkler et al.	552	549	7/11/97
	6,261,547	7/17/01	Bawa et al.	424	78.04	11/23/99
	6,309,375	10/30/01	Glines et al.	604	187	5/18/99
	6,322,548	11/27/01	Payne et al.	604	500	3/31/98
	6,352,667	3/5/02	English	264	328.17	8/24/99
	6,355,273	3/12/02	Carli et al.	424	489	8/4/00
	6,372,245	4/16/02	Bowman et al.	424	427	4/22/94
	6,375,659	4/24/02	Erbe et al.	606	94	2/20/01
	6,395,293	5/28/02	Polson et al.	424	426	3/8/00
	6,403,057	6/11/02	Schneider et al.	424	9.52	6/23/00
	6,417,201	7/9/02	Bardsley et al.	514	330	7/12/00
	6,426,339	7/30/02	Berde et al.	514	180	4/3/00
	6,432,415	8/13/02	Osborne et al.	424	400	12/17/99
	6,423,818	7/23/02	Matsuda et al.	528	354	7/26/00
	6,451,346	9/17/02	Shah	424	486	12/23/98
	6,543,081	3/18/03	Goldenheim et al.	424	426	4/2/01
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INFORMATION DISCLOSURE CITATION Sheet 1 of 5 PTO-1449			ATTORNEY'S DOCKET NO.: ARC 3119 R1		APPLICATION NO.: 10/628,984	
			APPLICANT: Chen et al.			
			FILING DATE: 07/28/03	GROUP: Unassigned		
US PATENT DOCUMENTS						
	US 2001/0004644 A1	6/21/01	Levin	514	646	12/15/00
	US 2001/0046518 A1	11/29/01	Sawhney	424	486	8/14/98
	US 2001/0055607 A1	12/27/01	Levin	424	435	7/17/98
	US 2002/0015712 A1	2/7/02	Mchrude et al.	424	400	5/23/00
	US 2002/0001608 A1	1/3/02	Polson et al.	424	426	3/8/00
	US 2002/0010150 A1	1/24/02	Cortese et al.	514	54	4/26/01
	US 2002/0016338 A1	2/7/02	Mather et al.	514	317	10/1/01
	US 2002/0028243 A1	3/7/02	Masters	424	484	2/28/01
	US 2002/0028181 A1	3/7/02	Miller et al.	424	43	4/26/01
	US 2002/0037104 A1	11/1/01	Zhang et al.	604	502	2/28/01
	US 2002/0037358 A1	3/28/02	Barry et al.	427	2.1	10/18/01
	US 2002/0039594 A1	4/4/02	Unger	424	426	5/11/98
	US 2002/0004063 A1	1/10/02	Zhang	424	443	9/28/99
	US 2002/0045668 A1	4/18/02	Dang et al.	514	649	7/17/01
	US 2002/0054915 A1	5/9/02	Goldenheim et al.	424	497	4/2/01
	US 2002/0061326 A1	5/23/02	Wei-Ping Li et al.	424	424	1/2/01
	US 2002/0086971 A1	7/14/02	Pham	528	354	2/1/02
FOREIGN PATENT DOCUMENTS						
	WO 93/24150	PCT				
	WO 95/13799	PCT				
	WO 98/27962	PCT				
	WO 98/27963	PCT				
	WO 99/47073	PCT				
	WO 00/74650 A2	PCT				
	WO 02/058670 A1	PCT				
	WO 02/067991 A1	PCT				
	WO 03/041685 A1	PCT				
	WO 03/041684 A2	PCT				
	WO 03/041757 A2	PCT				
OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages etc.)						
	Cleland, J. L. "Injectable Gels for Local and Systemic Delivery of Proteins," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u>, Vol. 28, 2001.					
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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages etc.)			
	Blanco, M. D. et al. "Bupivacaine-loaded comatrix formed by alumin microspheres included in a poly(lactide-coglycolide) film: in vivo biocompatibility and drug release studies," <u>Biomaterials</u> , Vol. 20, pp.1919-1924, 1999.		
	Duenas, E. et al. "Sustained Delivery of rhVEGF from a Novel Injectable Liquid, Plad" <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.		
	Guevello, P. Le et al. "High-performance liquid chromatographic determination of bupivacain in plasma samples for biopharmaceutical studies and application to seven other local anaesthetics," <u>Journal of Chromatography</u> , Vol. 622, pp. 284-290, (1993).		
	Garry, M. G. et al. "Evaluation of the efficiency of a bioerodible bupivacaine polymer system on antinociception and inflammatory mediator release," <u>Pain</u> , vol. 82, pp. 49-55, 1999.		
	Lambert, W. J. et al. "Development of an in situ forming biodegradable poly-lactide-co-glycolide system for controlled release of proteins," <u>Journal of Controlled Release</u> , Vol. 33, pp. 189-195 (1995).		
	Okumu, F. W. et al. "Sustained Delivery of Growth Hormone from a Novel Injectable Liquid, Plad," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.		
	Okumu, F. W. et al. "Evaluation of the Saber™ Delivery System for Sustained Release of Growth Hormone – Formulation Design and <i>In Vivo</i> Assessment," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.		
	Philip, B. K. et al. "The Economic Impact of Opioids on Postoperative Pain Management," <u>Journal of Clinical Anesthesia</u> , Vol. 14, pp. 354-364, 2002.		
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